



Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting <http://www.cms.hhs.gov/NationalProvIdentStand/> on the CMS web site.

MLN Matters Number: MM5057

Related Change Request (CR) #: 5057

Related CR Release Date: June 23, 2006

Effective Date: May 16, 2006

Related CR Transmittal #: R60NCD and R992CP

Implementation Date: July 17, 2006 (carriers); October 1, 2006 (FIs)

Lumbar Artificial Disc Replacement (LADR)

Provider Types Affected

All physicians and providers who bill Medicare carriers and fiscal intermediaries (FIs) for LADR

Providers Action Needed

This article and Change Request (CR) 5057 provide specific information regarding the new national coverage determination (NCD) for LADR. The message is three-pronged:

- 1) Effective May 16, 2006, the LADR with the Charite lumbar artificial disc is not covered by Medicare for beneficiaries over 60 years of age, i.e., on or after the beneficiary's 61st birthday;
- 2) Medicare coverage under the investigational device exemption (IDE) and/or clinical trial policy for other lumbar artificial discs is not impacted by this decision and such coverage continues if the billing requirements are met and the appropriate codes are submitted; and
- 3) For patients 60 years of age and younger, there is no NCD, leaving such determinations to continue to be made by the local contractors.

Background

The Centers for Medicare & Medicaid Services (CMS), upon completion of a national coverage analysis (NCA) for LADR, determined that LADR with the Charite lumbar artificial disc is not reasonable and necessary for Medicare patients

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over 60 years of age and is, therefore, non-covered for this patient population. For Medicare beneficiaries 60 years of age and younger, there is no NCD, leaving such determinations to be made by the local Medicare carrier or FI.

This NCD focuses on the LADR with the Charite lumbar artificial disc because it is the only United States Food and Drug Administration (FDA) approved lumbar artificial disc at this time. The FDA has approved the use of the Charite artificial disc for spine arthroplasty in skeletally mature patients with degenerative or discogenic disc disease (DDD) at one level for L4 to S1.

The addition of section 150.10 of Pub.100-03 is an NCD. NCDs are binding on all carriers, FIs, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4), effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

Billing Requirements

The following are the billing requirements for LADR according to the revised *Medicare Claims Processing Manual*, Chapter 32, Section 170, which is effective May 16, 2006.

- Assuming the providers bill separately, physicians and hospitals need to **issue the appropriate liability notice**, (Advance Beneficiary Notice (**ABN**) or Hospital Issued Notice of Non-coverage (**HINN**), to beneficiaries over 60 years of age who choose to have this procedure using the Charite lumbar artificial disc.
- The following language should be included in the ABN:
 - Under the "Items or Service" Section: Lumbar Artificial Disc Replacement (LADR) with the Charite Lumbar Artificial Disc.
 - Under the "Because" Section: After a national coverage analysis (NCA), Medicare issued a national coverage determination (NCD) (Section 150.10 of *Medicare NCD Manual*) that stated that LADR with the Charite Lumbar Artificial Disc is not reasonable and necessary for Medicare beneficiaries over 60 years of age. Therefore, LADR with the Charite lumbar artificial disc is non-covered for beneficiaries over 60 years of age. Medicare never pays for this service for this Medicare population.
- Hospitals need to have a **beneficiary who is over 60 years of age sign a HINN** if he/she wishes to have the procedure done when a Charite lumbar artificial disc is used in the procedure. If the beneficiary is not informed prior to admission that he or she is financially liable for the admission, the provider is liable.

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Information for Providers Billing Carriers

- For patients over 60 years of age, claims submitted with Category III Codes 0091T (Single interspace, lumbar) and/or 0092T (Each additional interspace) will be denied unless performed under an approved IDE/clinical trial. **(Note:** The Charite lumbar artificial disc is the only artificial disc approved by the Food and Drug Administration, therefore the procedure (0091T or 0092T) would be using the Charite unless under an IDE/clinical trial.)
- For patients over 60 years of age for procedures performed under the IDE/clinical trial and approved by the contractor, claims submitted with 0091T or 0092T and the modifier QA will be allowed and normal claims processing criteria for IDEs/clinical trials will be followed.

Information for Providers Billing FIs

For patients over 60 years of age, claims submitted with ICD-9 CM procedure code 84.65 (Insertion of total spinal disc prosthesis, lumbosacral) is never payable and will be denied unless performed under an approved IDE/clinical trial.

For patients over 60 years of age for procedures performed under the IDE/clinical trial and approved by the contractor, the FI will pay for LADR only when submitted with ICD-9 procedure code 84.65 with condition code 30 and diagnosis code V70.7 when submitted on type of bill (TOB) 11X.

- For services submitted on TOB 11X in critical access hospitals (CAH), the payment will be 101% of reasonable cost.
- For services submitted on TOB 11X from inpatient hospitals, including Indian Health Services (IHS) inpatient hospitals, will be paid under IPPS based on the DRG.
- For services submitted/performed on TOB 11X, IHS CAHs will be paid under 101% facility specific per diem rate.

Medicare Summary Notice (MSN) and Claim Adjustment Reason Code Messages for Denied Claims

- The following MSN: 21.24 will be issued: "This service is not covered for patients over age 60." along with a Claim Adjustment Reason Code such as: 96 "Non covered charge(s)."

Implementation

The implementation date for this instruction is July 17, 2006, for claims submitted to carriers and October 1, 2006, for claims submitted to Medicare FIs. But, in both instances, the change applies to services provided on or after May 16, 2006.

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Additional Information

The official instructions issued to your Medicare carrier and intermediary regarding this change are in two transmittals for CR5057. Transmittal R60NCD contains the NCD instructions and can be found at <http://www.cms.hhs.gov/Transmittals/downloads/R60NCD.pdf> on the CMS web site. The claims processing instructions are in Transmittal R992CP, which is at <http://www.cms.hhs.gov/Transmittals/downloads/R992CP.pdf>.

If you have questions, please contact your Medicare intermediary or carrier at their toll-free number, which may be found at <http://www.cms.hhs.gov/apps/contacts/> on the CMS web site.

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